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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,291	11/30/1999	LIEPING CHEN	07039-187001	8838
26191	7590	11/10/2003	EXAMINER	
FISH & RICHARDSON P.C. 3300 DAIN RAUSCHER PLAZA 60 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402			SOUAYA, JEHANNE E	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/451,291	CHEN, LIEPING	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,11-13,36,37 and 46-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5,11-13,36 and 37 is/are allowed.
- 6) ☒ Claim(s) 46-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1, 5, 11-13, 36, 37, and 46-51 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The amendments to claims 1, 5, 11-13, 36 and 37 have overcome the rejection under 35 USC 102(e) made in the previous office action. Accordingly, claims 1, 5, 11-13, 36, and 37 are allowable. Any rejections not reiterated are hereby withdrawn. The following rejection is reiterated with respect to claims 46-51. It constitutes the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 103

3. Claims 46-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al in view of Romanos et al.

Freeman et al teach B7-4 polypeptides such as the polypeptide sequence of SEQ ID NO 4, which is encoded by the polynucleotide of SEQ ID NO 3 (see sequence listing, claims). SEQ ID NOS 3 and 4 of Freeman et al are identical to SEQ ID NOS 2 and 1, respectively of the instant application.

Freeman et al do not specifically teach an isolated DNA comprising a nucleic acid encoding a polypeptide consisting of instantly pending SEQ ID NO 1 but lacking amino acids 1-22, however Freeman et al do teach constructing vectors for inducible expression of B7-4 protein in eukaryotic cells, such as yeast (p 17, col. 2, end of para 0156 and para 1059). It is further noted that amino acids 1-22 of instantly claimed SEQ ID NO 1 is taught by the instant specification to be a signal peptide. Furthermore, methods of cloning and expressing proteins with that contain a signal peptide in foreign host cells such as yeast, were known in the art at the time of the invention. For example, Romanos et al ("Expression of cloned genes in yeast" from Cloning 2: A practical Approach, IRL press, 1995, chapter 5, pp 133-148) teach proteins can be expressed in *S. cerevisiae* wherein the signal peptide of the protein is removed and placed in a secretion vector which expresses a fusion protein (yeast signal peptide joined to the foreign protein lacking it's own signal peptide) (see p. 134-135). Romanos et al teach that such can be useful, for instance, to express foreign proteins secreted to a high level which may only need minimal purification. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to construct a DNA molecule, for example for expression in yeast, as taught by Freeman et al, wherein the DNA molecule comprised a vector which contained a signal peptide specific to the foreign host and a nucleic acid encoding SEQ ID NO 4 of Freeman et al (SEQ ID NO 1 of the instantly claimed invention) minus the signal peptide of SEQ ID NO 4 as Romanos et al teach that such is necessary when expressing proteins with signal peptides in foreign hosts. Although Freeman et al do not teach a specific peptide signal sequence, and instead teach that SEQ ID NO 4 of Freeman et al contains a signal peptide at "about amino acids 1-18" (see p. 11, col. 1, para 0109), it would have further been prima facie

obvious to one of ordinary skill in the art at the time the invention was made to construct a number of different vectors comprising different fragments of SEQ ID NO 4 to determine the construct minus the complete signal sequence of SEQ ID NO 4 as Freeman et al only teach an approximate range of nucleic acids. Such constructs would include a nucleic acid encoding SEQ ID NO 4 of Freeman et al minus the first 22 amino acids as the ordinary artisan would have realized that without a specific range, a number of different constructs would have to be made to determine the exact signal sequence, such as constructs \pm 4-5 amino acids on either side of the range, and arrive at the construct and method of making the polypeptide encoded by the construct of the instantly claimed invention.

The response traverses the rejection. The response asserts that given the teachings of Freeman et al, if one of ordinary skill in the art wished to make a construct containing a nucleic acid sequence encoding the mature B7-H4 sequence, such an artisan would likely make a construct encoding a polypeptide lacking amino acids 1-18 and that there would be no reason to contemplate making a construct containing less B7-H4 amino acids than specifically disclosed by Freeman et al as he or she would likely be concerned about the possibility of "missing" on or more amino acids. The response further asserts that there exists no motivation in Freeman to create a construct specifically lacking codons 1-22 of SEQ ID NO: 1. This argument was thoroughly reviewed but was not found persuasive. As stated in the previous office action, because Freeman et al only teaches a range of amino acids that are the signal sequence, the ordinary artisan would have been to construct a number of different vectors comprising different fragments of SEQ ID NO 4 of Freeman et al to determine the construct minus the complete signal sequence of SEQ ID NO 4 taught by Freeman et al. Such constructs would include a

nucleic acid encoding SEQ ID NO 4 of Freeman et al minus the first 22 amino acids as the ordinary artisan would have realized that without a specific range, a number of different constructs would have to be made to determine the exact signal sequence, such as constructs +/- 4-5 amino acids on either side of the range, and arrive at the construct and method of making the polypeptide encoded by the construct of the instantly claimed invention. The rejection is maintained.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Claims 1, 5, 11-13, 36, and 37 are allowable. Claims 46-51 are rejected under 35 USC 103(a).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (703) 308-

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6565. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name. It is also noted that after January 12, 2004, the examiner will be located at the new USPTO campus and will be reachable at telephone number (571) 272-0752.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne (Souaya) Sitton

Primary Examiner

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11/7/03